QUALITY SYSTEMS VERIFICATION PROGRAM GENERAL POLICIES AND PROCEDURES

General

This instruction provides policies and procedures for providing service under the Quality System Verification Program (QSVP). The QSVP is a voluntary, user-fee service, available to processors of agricultural products, that is designed to provide independent verification that special processes or marketing claims are clearly defined and verified by an independent third party.

QSVP services are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review and Compliance (ARC) Branch, Quality Systems Verification Program (QSVP), under the authority of the Agricultural Marketing Act of 1946, as amended; the Code of Federal Regulations (CFR) 7, Part 54; and as detailed in specific program descriptions.

Scope

These policies and procedures apply to all ARC Branch audit-based programs as referenced in specific program descriptions. Program requirements are set forth in specific program descriptions and the appropriate program guidelines. Copies of these documents are available by contacting the ARC Branch office at (202) 720-1124 or on the USDA's Internet website at: http://www.ams.usda.gov/lsg/arc/audit.htm.

Requesting Service

Any person with a financial interest in agricultural products or related services may apply for service under this program. To apply, applicants must:

(1) Complete LS Form 313, Application for Service, and send it to the Meat Grading and Certification Branch Office of Field Operations (OFO) in Denver, CO, at the address shown on the form. For faster service, applicants may fax the form to the Washington ARC Branch office at (202) 690-4119, but must send the form with the original signature to the OFO.

(2) Submit a cover letter requesting QSVP services, along with a complete copy of the applicant's program documentation, as described in the appropriate general requirements document, to the QSVP Manager, ARC Branch, LS Program, 1400 Independence Avenue, S.W., STOP 0248, Room 2628-S, Washington, DC, 20250-0248. Applicants must include the following information when submitting their program documentation for consideration:

- Examples of all labels, tags or other instruments used to identify animals or products.
- Completed examples of all forms used in the program. These examples should be taken from actual records.
- Copies of letters from consulting veterinarians, feed manufacturers, tag manufacturers, etc., as specified in the appropriate general requirements documents.

- A copy of the most recent internal audit report. All programs that specify internal audits as a program requirement must complete a satisfactory internal audit and record the findings before contacting USDA for review and approval services.

The applicant may withdraw from the application process at any time. Applicants will be responsible for any hourly fees or other costs accrued prior to withdrawing their application from further consideration.

Receiving Applications
The QSVP office will receive and review applications for completeness and store a copy of the information in the applicant's file. If any information is missing, the QSVP office will contact the applicant to request any additional information necessary. The QSVP office will withhold the application from further processing until the necessary information is received.

Once the QSVP office has determined that the application packet is complete, the request for service and accompanying program documentation will be forwarded to the assigned auditor and the applicant will be notified of the status of the application.

Document Reviews
The assigned auditor will conduct a complete adequacy audit of the applicant's program documentation to ensure that each element of the specific program description has been fully addressed and complies with the appropriate program requirements.

If the program documentation is adequate, the auditor will arrange to conduct an onsite audit. If any element of the program documentation requires clarification that can be easily obtained by working directly with the applicant, the auditor will contact the applicant and request additional information.

If the applicant's program information is grossly deficient, the auditor will prepare and submit a memorandum itemizing the deficiencies to the QSVP Manager. The Manager will determine whether to return the manual to the applicant for further development or notify the applicant and retain the manual in anticipation of receiving revised or additional information.

Onsite Audits
After the applicant has been notified that the program documentation is adequate, the Lead Auditor will notify the applicant of the following information:
(1) Proposed date(s) and itinerary of the onsite audit.
(2) Projected cost of the audit, including hourly fees, per diem, and travel expenses.
(3) Names of the audit team members.

AMS auditors will travel to each program location and conduct a detailed audit. At each location, the auditor will:

(1) Interview management personnel and employees with specific responsibilities relative to the program to verify their knowledge of program requirements, their role in the system, and the roles and responsibilities of other persons involved in the system.

(2) Determine if additional onsite audits will be required to validate procedures.
(3) Review written procedures and supporting documentation.
(4) Establish positive traceability of livestock or products on hand as appropriate.
(5) Conduct reviews of applicant's supporting businesses such as further processors, consulting veterinarians, feed producers, animal health product producers, as deemed necessary by the lead auditor to ensure compliance.

In order to reduce travel expenses and time required onsite, the Lead Auditor may elect to conduct phone interviews and request fax or e-mail copies of specific program documentation or records prior to arrival onsite as part of the official audit.

Audit Reports
Upon completion of the onsite audit, the auditor will prepare a detailed report of the audit observations, findings, and recommendations to the QSVP Manager. The report will include, at a minimum:
(1) Organizational structure of the business
(2) Scope of the operation
(3) Identification procedures
(4) Livestock or product segregation procedures
(5) Traceability procedures
(6) Training methods used
(7) Involvement of other parties (veterinarians, feed producers, outside auditor, subcontractors, etc.)
(8) Recommendation regarding approval

Auditors will itemize any significant findings of nonconformance in the findings section of the audit report and assign a tracking number to each nonconformance. Auditors will classify each itemized nonconformance as either a *continuous improvement point* or *hold point* according to the following definitions:

Continuous improvement point (CIP): a minor nonconformance that, although it needs to be corrected in a timely manner, does not compromise the integrity of the program. Isolated incidences of nonconformance should be considered continuous improvement points.

Hold point: a major nonconformance that compromises the integrity of the program to the extent that program approval should be denied, revoked, or delayed until corrective action can be completed. Any absence or complete breakdown in a required element should be considered a hold point. An accumulation of continuous improvement points may also result in the assignment of a hold point for an audit.

All audit findings, including recommendations to be sent forward to the QSVP Manager, will be discussed with the applicant at the conclusion of the audit. Auditors will then submit a complete report of the audit to the QSVP Manager for final review and disposition.

Approval. Applicants that meet all program requirements will be issued approval valid for 1 year from the date of the onsite audit. If approved, the QSVP Manager will add the applicant to the list of

approved QSVP program applicants as described in **Publication of Approval Status**.

Conditional Approval. If the onsite audit finds only minor nonconformances (CIP's) to the applicant's stated procedures or QSVP program requirements, the QSVP Manager may issue approval with requirements for additional document and/or onsite reviews be conducted at the applicant's expense after 6 months.

Denied Approval. The QSVP Manager may deny approval for any of the following reasons:
(1) Failure to adequately address any program documentation requirement.
(2) Failure to demonstrate capability to meet any program requirement during the onsite audit.
(3) Denying access to applicant's facilities and records within the scope of the requested approval.
(4) Presenting false or misleading information to any ARC Branch official at any point in the review or approval process.
(5) Finding of any objective evidence of nonconformance within the scope of the requested approval.

Certification
Upon reaching a decision, the QSVP Manager will issue a letter to the program's management representative regarding the decision to approve, conditionally approve, or deny approval, stating any terms and conditions, as appropriate. The letter will include references to all audit memorandums and reports or other information on which the approval decision was based. Approved applicants should retain the approval letter for their records.

Approval may be issued with specified actions to be taken by the applicant within a given time period. Applicants must complete corrective actions and submit written responses within the time frames specified in the applicant's approval letter. At the conclusion of the specified time period, the QSVP Manager may require a document review or onsite audit of the program of sufficient detail to ensure all program requirements are met. If the follow-up audit finds all nonconformances have been adequately addressed, and no new nonconformances raised, the QSVP Manager will issue approval as described above in Approval. If the follow-up audit finds all previously identified nonconformances have been adequately addressed, but new minor nonconformances are identified, the QSVP Manager may issue conditional approval as described in Conditional Approval. If the follow-up audit finds previously identified nonconformances have not been corrected, the applicant will be removed from the list of approved applicants until corrective actions are completed and confirmed by an additional audit.

Cancellation. Approved suppliers may cancel service at any time by notifying the QSVP Manager in writing. Applicants who cancel service will be removed from the list of approved QSVP applicants, and must reapply and be approved through an audit before they will be returned to the list.

Publication of Approval Status
Information about the approval status of an applicant's operation will be posted on the list of approved QSVP applicants at: http://www.ams.usda.gov/lsg/arc/audit.htm. The posting will include the following information:
1. Name and contact information for each approved program participant
2. Type of services or products approved
3. Approval or certificate number

4. Effective date of approval
5. Renewal date

Labeling
When permitted under specific program guidelines, approved applicants may use the "USDA Process Verified" shield or the term USDA Process Verified when labeling and promoting eligible products. Use of the USDA Process Verified shield must always be in direct association with a clear description of the processes verified under the applicant's program. Applicants who wish to use the USDA Process Verified shield must provide for the proper control and use of the shield on labels, packaging, and other marketing material on which it may appear, in their original request for program approval.

Maintaining Approved Programs
Applicants are required to maintain their programs as described in their approved program documentation. Any changes to the applicant's approved system that may potentially affect the quality or integrity of QSVP services or products, must be submitted in writing to the QSVP Manager and approved prior to implementation. Depending upon the nature and extent of the changes, the QSVP Manager may require a complete or partial onsite audit of the system prior to approval. In situations where an additional onsite audit is required, a new approval will be issued for an appropriate time period based on the findings of the audit.

Surveillance
All approved programs are subject to unannounced reviews by ARC Branch representatives. The auditor in an official memorandum to the QSVP Manager will document the findings of unannounced reviews. Findings of unannounced reviews will be considered when determining compliance of the program for ongoing approval, or renewal, or may provide the basis for suspension.

ARC Branch representatives will review the use of official QSVP terminology and control of products during routine label reviews under Public Law 272. Improper use of QSVP logos or terminology will be documented and referred to the QSVP Manager for action.

Renewal of Certification or Approval
Applicants should contact the QSVP office in Washington, DC, at least 90 days before the expiration of their approval to request renewal. Upon request, the QSVP Manager will arrange for a document review and onsite audit to be conducted at a time as near the renewal date as possible while coordinating the audit with other audits in the area. Each applicant must submit any revised copies of program documentation, and be reassessed as described in this instruction to maintain approved status.

Suspending Approval
The QSVP Manager may suspend approval and remove an applicant's program from the list of approved QSVP applicants for any of the following reasons:
(1) Failure to follow applicant's approved policies and procedures.
(2) Implementing significant changes to approved systems without prior written notification to the ARC Branch.
(3) Deliberate misrepresentation of the eligibility of livestock or products distributed under an approved program.

(4) Confirmed finding of any prohibited compounds or substances or other violations as described in the appropriate program's general requirements. Upon confirming the violation, AMS will suspend all approvals for applicants in the product's chain of custody pending a complete investigation, in cooperation with appropriate regulatory agencies.
(5) Denying access to applicant's facilities and records within the scope of the requested approval.
(6) Failure to respond to corrective actions in the timeframe provided.
(7) Failure to pay ARC Branch fees.

The QSVP Manager will notify the applicant in writing of the suspension and details on actions required to regain approval status. Information provided will not include specific remedies to barriers to certification.

Reinstatement of Suspended Approval
Approvals suspended for implementing changes to the applicant's system without the required advance notifications will be reinstated immediately upon receipt of appropriate corrective action.

AMS will reinstate approvals for applicants whose systems are within the chain of custody of products identified as containing or having been treated with any prohibited substance only upon revalidation of the integrity of their program in cooperation with appropriate regulatory agencies.

Approvals for applicants found to be responsible for the introduction of prohibited substances into the affected livestock or products will be suspended until such a time as the applicant provides objective evidence that their system has been completely purged of all potentially affected product and an onsite audit verifies that effective corrective action has been taken. Final decisions on the suitability of corrective action and the applicant's eligibility for reinstatement is at the discretion of the QSVP Manager.

Approvals for applicants suspended for failure to pay ARC Branch fees will be reinstated upon notification from the Denver OFO that all outstanding fees and interest have been paid in full.

Appeals, Complaints and Disputes
Applicants have the right to question or appeal any adverse audit findings or decisions issued by the QSVP Manager. Appeals, complaints, and disputes must be submitted in writing to the ARC Branch Chief, Washington, DC, within 30 days of the date of the official report or letter rendering the findings or decisions. Requests for appeals must include:
(1) The basis for the appeal, complaint, or dispute
(2) The requested alternative decision or actions.

The ARC Branch Chief will review any request for action and notify the applicant of the final decision within 30 working days of the receipt of the request. Any suspensions or denied approvals will remain in effect pending the outcome of the appeal.

Fees for Service
The cost of QSVP document reviews, onsite compliance audits, and any follow-up or surveillance audits, including auditing and travel time, per diem, and related expenses, are the responsibility of the party requesting the service.

Fee rate. Fees charged for service will be charged according to the approved hourly rate published in the *Federal Register* http://www.access.gpo.gov/nara/index.html . Hourly fees will be assessed for official time required to prepare for, conduct, and report the results of assessments, and time required to complete all related travel.

Audit preparation. Applicants will be billed for official time spent preparing for quality system audits performed on their behalf. Official preparation time will include review of approved quality manuals and records from previous audits, and preparation of checklists.

Travel. Applicants will be charged for travel time and expenses to and from the assigned auditor's official duty location and between audit sites. When traveling to provide service to multiple applicants, charges will be prorated between the applicants.

Recording hours charged. Hours of service to be charged to the applicant will be documented on LS Form 5-3 (1-93), Agricultural Products Certificate, and submitted to the OFO for billing. Copies of the charge certificate will be maintained with the audit working papers.

Document Control and Retention

Records relating to services provided under the QSVP Program are stored and maintained as follows:

LS 313 - Requests for Service:	Original filed in the OFO. Electronic version filed in QSVP office. Copies retained until the applicant withdraws request for service.
Audit reports:	Electronic version filed in QSVP office. One copy sent to applicant with approval letter. Copies retained for at least 6 years.
Approval letters:	Signed original sent to applicant. Electronic version filed in QSVP office. Copies retained for at least 6 years.

Auditors

Auditors assigned to conduct document reviews and onsite audits must be qualified as ARC Branch lead auditors as described in ARC Instruction 1030, Training and Experience Requirements for Quality System and Compliance Audits. Auditors must have signed conflict of interest statements and appropriate disclosure agreements on file with the ARC Branch prior to assignment to provide service to a specific applicant.

Larry R. Meadows, Acting Chief
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